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Subject: Compliance Option for Periods of Planned Routine Maintenance for a Centralized Combustion Control Device at Pharmaceuticals Production Facilities
Pharmaceuticals Production NESHAP
ESD Project No. 93/50; MRI Project No. 104804.1.056

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To: Project File

I. Introduction

This memorandum presents an analysis of a potential compliance option for periods of planned routine maintenance of a centralized combustion control device (CCCD) that is used to control emissions from process vents that are part of an affected source under the Pharmaceuticals Production NESHAP. The results of this analysis show that the option is equivalent to the MACT floor (i.e., it reduces HAP emissions by 93 percent).

II. Background

Some existing pharmaceutical production facilities use a CCCD because they have found that it is more reliable and efficient than multiple point-of-use devices. However, during periods of planned routine maintenance of a CCCD (or any control device), the promulgated pharmaceuticals production NESHAP requires processes that vent to the device either to be shutdown or emissions must be routed to another control device that achieves the same control efficiency as the CCCD. This requirement may result in inefficient and costly operation for a facility that uses the CCCD to control multiple non-dedicated processes. One reason for the inefficiency is that all of the processes cannot be sequenced to shutdown simultaneously. In addition, it is impractical to have an in-house staff large enough to conduct maintenance on all of the shutdown processes simultaneously (as well as on the CCCD). Therefore, the industry has requested that EPA amend the rule to include a compliance option that would allow the use of backup condensers during periods of planned routine maintenance of a CCCD that is used to control emissions from non-dedicated processes.

III. Discussion

A. Description of Planned Routine Maintenance Option

In response to the industry concern, EPA has developed an option that would allow use of condensers during periods of planned routine maintenance. Under this option, each process vent with organic HAP emissions greater than 15 lb/d must be routed through a closed-vent system to the condenser. The condenser must be operated at a temperature less than or equal to -50°C when the partial pressure of the HAP in the emission stream is greater than 20 kPa, and it must be operated at a temperature less than or equal to -5°C when the partial pressure of the HAP in the emission stream is less than or equal to 20 kPa. The HAP partial pressures must be determined at 25°C. These requirements are comparable to State RACT programs that are based on the generalized control program described in the 1978 Control Techniques Guideline Document for Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products.

The planned routine maintenance option also would require control of HCl emissions in process vent streams that normally are controlled in scrubbers that follow the CCCD. The requirement is that process vents with HCl emissions greater than or equal to 15 lb/d be routed through a closed vent system to a caustic scrubber.

B. Performance of Planned Routine Maintenance Option

To evaluate the level of control that would be achieved, we assumed that the fraction of the total nationwide organic HAP emissions that is controlled with CCCDs is the same for each organic HAP emitted from process vents. Another assumption is that emission streams containing multiple HAP have HAP partial pressures greater than 20 kPa if any individual HAP in the stream has a vapor pressure greater than 20 kPa. Thus, we applied the planned routine maintenance option requirements to the nationwide emissions of all organic HAP (see chapter 5 of the Basis and Purpose document). These emissions are also presented in the attachment to this memorandum. The attachment also shows the vapor pressures at -50°C or -5°C, depending on whether the vapor pressure is greater than or less than 20 kPa (150 mm Hg), respectively. The vapor pressures for most of the HAP were estimated by extrapolating between tabulated values in the Chemical Engineering Handbook. Vapor pressures for triethlyamine and dimethlyformamide were estimated using Antoine's equation because tabulated values were not available. Vapor pressures were not estimated for methyl chloride and ethylene oxide because these compounds are gases at 25°C and a percent reduction could not be determined; however, these compounds account for only a small percentage of the total emissions.

The results of this analysis show that the overall control efficiency of the planned routine maintenance option is 93 percent for organic HAP emissions. Hydrochloric acid and chlorine emissions would easily be controlled to an even higher efficiency in a caustic scrubber.

IV. Conclusion

The compliance option for periods of planned routine maintenance of a CCCD is acceptable because the overall control efficiency is estimated to be at least as stringent as the MACT floor for process vents.

HAP	Uncontrolled emissions, lb/yr	Major emissions	Fraction of emissions	Vapor pressures, mm Hg			Fraction reduction		
				25C	-5C	-50C			
MeCl2	43,563,278	43,563,278	0.526	419.5		6.2		0.9852	0.51848
MeOH	18,270,408	18,270,408	0.221	127.94	21.82			0.8295	0.18307
Toluene	10,559,263	10,559,263	0.128	29.85	3.94			0.8680	0.11072
HCl	7,306,362								
MIBK	4,213,926	4,213,926	0.051	7.6	0.32			0.9579	0.04876
Hexane	2,498,277	2,498,277	0.030	158.2		1.2		0.9924	0.02995
Dimethylformamide	1,311,981	1,311,981	0.016	4	0.407			0.8983	0.01424
Chloroform	742,215	742,215	0.0090	194.2		2.7		0.9861	0.00884
Acetonitrile	447,576	447,576	0.0054	92.8	20			0.7845	0.00424
Methyl chloride	328,752								
Triethylamine	310,235	310,235	0.0037	58	7.63			0.8684	0.00325
MEK	277,140	277,140	0.0033	100	22.4			0.7760	0.00260
EO	266,086								
CS2	255,442	255,442	0.0031	365.9		7.2		0.9803	0.00303
Methyl chloroform	178,902	178,902	0.0022	130.9	29.4			0.7754	0.00168
Chlorine	158,933								
Trichloroethylene	150,300	150,300	0.0018	77.5	15.5			0.8000	0.00145
Total		82,778,943							0.9303